REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claims 22, 38, and 39 have been amended and new claims 59-61 have been added. Therefore, claims 1-61 are pending.

Rejection under 35 U.S.C. § 102

Claims 1-7, 9-11, 12-15, 17, 18, 21, 22-34, 37-55 and 58 were rejected under 35 U.S.C. 102(a) as anticipated by Sirhan et al. (WO 2002/056790). This rejection is respectfully traversed.

Independent claims 1, 22, 38, and 39 all recite a polymer that has "at least one active agent incorporated into the polymer backbone."

Sirhan et al., relates to luminal prostheses which allow for controlled release of at least one therapeutic capable agent with increased efficacy to selected locations within a patient's vasculature to reduce restenosis. In Examples 1, 2, 3, and 8 of Sirhan et al. a drug was loaded onto a stent by spraying or dipping, and then a copolymer or barrier was deposited over the drug. In Example 4, a matrix solution including a matrix polymer and a therapeutic capable agent was coated onto a stent, and the stent was then coated or sprayed with a top coat of a rate-controlling barrier. In Example 7, a matrix solution including a matrix polymer (CAB) and a therapeutic capable agent (mycophenolic acid) were coated onto a stent, and the stent was then coated or sprayed with a top coat of a rate-controlling barrier (parylene). Sirhan et al. did not prepare any devices comprising a polymer with an active agent incorporated into the polymer backbone, nor did Sirhan et al. discuss how such a device could be made. Rather, the therapeutic capable agents of Sirhan et al. were coated onto a stent alone and then covered with a barrier layer, or they were incorporated into the matrix of a polymer that was coated onto a stent. At paragraphs [30] and [116] Sirhan et al. discusses polymeric materials that include therapeutic capable agent moieties as a structural subunits of the polymer, such as the polymers recited in independent claim 1, however, no specific examples of a device comprising such a polymer were prepared or specifically described in Sirhan et al.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference

between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

No devices comprising a polymer having "at least one active agent incorporated into the polymer backbone" were prepared or specifically described in Sirhan et al. Accordingly, Sirhan et al. does not anticipate the instant claims. It is respectfully submitted that the general discussion found at paragraphs [30] and [116] of Sirhan et al. does not describe any devices with enough specificity to anticipate the instant claims. Accordingly, withdrawal of the rejection of claims 1-7, 9-11, 12-15, 17, 18, 21, 22-34, 37-55 and 58 under 35 U.S.C. 102(a) over Sirhan et al. is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1, 19, 20, 35, 36, 56 and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. This rejection is respectfully traversed.

Claims 19, 20, 35, 36, 56, and 57 all recite thicknesses for the polymers therein.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. With regard to rejections under 35 U.S.C. 103, the Examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e. the reference teachings establish a *prima facie* case of obviousness) is more probable than not. M.P.E.P. 2142. It is respectfully submitted that the rejected claims are not *prima facie* obvious over the cited document, since Sirhan et al. does not teach all the elements of the rejected claims (e.g. the recited thicknesses).

At page 4 of the Office action, the Examiner acknowledges that Sirhan et al. does not teach the thickness of the coating. The Examiner goes on to conclude that "one having ordinary skill in the art would have reasonable expectation of success that coating the stent at prescribed thickness would provide desired release of the active agent from the coated stent." The Examiner has not identified any support for this conclusion. Accordingly, Applicant submits that the Examiner is taking "official notice." If the Office maintains the rejection over Sirhan et al. under 37 C.F.R. 1.104(d)(2), the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support this finding. Thus, if the

Office maintains the rejection, in the next communication Applicant respectfully requests that the Examiner provide an affidavit or declaration setting forth specific factual statements and explanation to support the conclusion that that one having ordinary skill in the art would have had a reasonable expectation that coating the stent at the prescribed thicknesses would have provide desired release of the active agent from the coated stent.

Because Sirhan et al. does not discuss the polymer thicknesses recited in the rejected claims and because the Examiner has not provided any evidence that the recited thicknesses would have been apparent to one of ordinary skill in the art, it is respectfully submitted that that Examiner has not met the initial burden to support a *prima facie* conclusion of obviousness. Accordingly, withdrawal of the rejection of claims 19, 20, 35, 36, 56, and 57 under 35 U.S.C. §103(a) over Sirhan et al. is appropriate and is respectfully requested.

It is noted that claim 1 was also included in the rejection under 35 U.S.C. §103(a) over Sirhan et al. However, the Examiner did not provide any discussion regarding how the reference was being applied to claim 1. Rather, at page 4 of the Office action, the Examiner noted that "Sirhan is described above as anticipating claim 1." As discussed herein above, Sirhan et al. does not anticipate claim 1. Accordingly, the only statement made by the Examiner in support of the rejection of claim 1 under 35 U.S.C. §103(a) over Sirhan et al. is inaccurate. Accordingly, it is respectfully submitted that that Examiner has not met the initial burden to support a *prima facie* conclusion of obviousness for claim 1. Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a) over Sirhan et al. is appropriate and is also respectfully requested.

New Claims 59-61

New claims 59-61 are directed to a stent comprising: 1) a first polymer comprising salicylic acid incorporated into the polymer backbone; and 2) a second active agent selected from paclitaxel and rapamycin that is dispersed within the polymer matrix of the first polymer. It is submitted that Sirhan et al. provides no suggestion of, or motivation to prepare such a stent. Support for new claims 59-61 can be found at original claims 13, 10, and 1, wherein the first active agent is the elected species salicylic acid.

CONCLUSION

The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

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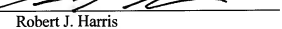
Date: January 7, 2009

By: 
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